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NBTY, INC.

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

TATIANA KOROLSHTEYN, on behalf of herself and all others similarly situated,

Plaintiff,

v.

COSTCO WHOLESALE CORPORATION, and NBTY, INC.

Defendants.

CASE NO.: 3:15-CV-00709-CAB-RBB

DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION TO EXCLUDE EVIDENCE, OPINIONS, AND TESTIMONY OF DEFENDANTS' EXPERT SUSAN MITMESSER

Date: TBD
Time: TBD
Judge: Hon. Cathy Ann Bencivengo
Courtroom: 4C

PER CHAMBERS RULES, NO ORAL ARGUMENT UNLESS SEPARATELY ORDERED BY THE COURT

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I. INTRODUCTION

Plaintiff's Motion is fatally flawed at its core because it is based on the incorrect legal standard. Plaintiff undeniably bears the burden of proof in this case. She must prove not only that the advertised health benefits of Defendants' Trunature Gingko Biloba with Vinpocetine product (the "Product") are false, but that they are universally false – i.e., the Product provides no benefits to ***anyone***, whether sick or healthy. That is the basis upon which she persuaded the Court to certify a class comprising of "all consumers."

Nevertheless, Plaintiff's Motion to exclude the opinions of Dr. Susan Mitmesser ("Mot.") contravenes these fundamental principles by using the wrong legal standard. Operating on the fallacious premise that Defendants bear the burden of substantiating the Product's claims, Plaintiff seeks to exclude Dr. Mitmesser's relevant and reliable opinions essentially because they do not help prove up Plaintiff's case.

For example, Plaintiff faults Dr. Mitmesser for "cherry-picking" only those studies which support the Product's claims. According to Plaintiff, she did not conduct a "totality of the evidence analysis" – i.e., include the studies cited by Plaintiff in her favor – to establish that "Defendants' claims about [the Product] were proven and thus truthful." Mot. at 5, 6. However, this is contrary to the controlling legal standard in a false advertising action. In an action such as this one, the **plaintiff** alone bears the burden of proving **falsity**, and the defendant has no obligation to prove anything, much less substantiate its label claims. Thus, as a matter of law, Dr. Mitmesser is not required to account for the studies upon which Plaintiff relies.

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Plaintiff also criticizes Dr. Mitmesser for relying on studies conducted upon diseased subjects,[1] the results of which Plaintiff claims cannot be reliably extrapolated to healthy individuals. But this critique misses the point. Even setting aside whether the testing data can be extrapolated, the fact of the matter is that Plaintiff has the burden of proving that the Product does not work for ***any*** member of the certified "all consumers" class, whether healthy or sick. As the Court noted in its Order Granting Plaintiff's Motion for Class Certification ("Order"), "Plaintiff's entire lawsuit rides on her claim that TruNature Gingko provides ***no*** benefits and that the statements on the product labels are false. ***The answer to these questions will be the same for the entire class.***" (Dkt. No. 158 at 10) (emphasis added). Accordingly, if Plaintiff cannot overcome the studies referenced by Dr. Mitmesser showing that the Product benefits the diseased population and affirmatively prove that the Product is ineffectual for that group, then Plaintiff's entire case falls apart. Therefore, the diseased population studies upon which Dr. Mitmesser relies are not just relevant—they are dispositive.

Lastly, the Motion also should not be granted on any of the remaining grounds that Plaintiff avers. Those objections, pertaining to issues such as testing methodology and Dr. Mitmesser's qualifications, largely bear on the weight of her opinions, not their admissibility. Moreover, some of the objections are baseless on their face, as they are hatched out of mischaracterizations of Dr. Mitmesser's deposition testimony and the studies she relies upon.

For the foregoing reasons and others referenced below, Plaintiff's Motion should be denied in its entirety.

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[1] The reference to a "diseased" population may be overbroad to the extent it includes populations who are merely suffering from cognitive decline or mild cognitive impairment, a condition which may or may not be classified as a disease.

II. ARGUMENT

A. Dr. Mitmesser's Opinions are Relevant to the Issues in This Falsity Case

1. *Plaintiff misapprehends the relevant standard in a falsity case.*

As explained more fully in Defendants' recently filed Motion for Summary Judgment (Dkt. No. 172), there are material differences between the legal standard that governs lack of substantiation versus falsity cases – differences which are critical to the Court's decision on the instant Motion. Specifically, challenges based on a lack of substantiation are not available to private plaintiffs under California law; such actions are "left to the Attorney General and other prosecuting authorities . . ." *Nat'l Council Against Health Fraud v. King Bio Pharm., Inc.*, 107 Cal. App. 4th 1336, 1344–45 (2003). In lack of substantiation actions, the burden rests upon the defendant to come forward with evidence justifying its advertising claims. *Id*. at 1345 (prosecutor can "require advertiser to substantiate advertising claims"). And, in doing so, the defendant may be required to satisfy the "totality of the evidence" standard that is promulgated by the Federal Food and Drug Administration ("FDA").[2]

The burden is different in a falsity case brought by a private plaintiff, however. In a case like this one, "Plaintiff [must] adduce evidence sufficient to

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[2] In the FDA's Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act ("FDA's Substantiation Guidance"), the FDA recommends looking at four issues "[i]n determining whether the *substantiation standard* has been met with competent and reliable scientific evidence." FDA, *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act*, at II.A (2008) ("FDA Guidance") (emphasis added), https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073200.htm. The "totality of the evidence" is one of these four issues to be evaluated under the *substantiation* standard – which clearly does not govern this case. *Id.*

present to a jury to show that Defendant's advertising claims with respect to [the] Product are actually false; not simply that they are not backed up by scientific evidence." *Fraker v. Bayer Corp*., 2009 WL 5865687, at *8 (E.D. Cal. Oct. 6, 2009). To establish falsity, Plaintiff must show "that ***all scientists agree***" the product at issue fails to provide the advertised benefits. *In re GNC Corp.*, 789 F.3d 505, 515 (4th Cir. 2015) (emphasis added).[3]

On the other hand, the defendant in a falsity case has **no** burden to produce any evidence or substantiate the truth of its products' claims. *King Bio*, 107 Cal. App. 4th at 1345 ("private plaintiffs are not authorized to demand substantiation for advertising claims"). Moreover, the plaintiff cannot satisfy its burden of proving claims are false by taking issue with a defendant's support for those claims – to allow that is to "improperly shift[] the burden of substantiation to Defendants." *Reed v. NBTY, Inc*., 2014 WL 12284044, at *14 (C.D. Cal. Nov. 18, 2014). Rather, "[w]here there are studies demonstrating both the effectiveness and ineffectiveness of the Products," then, as a matter of law, "a reasonable jury could not find that the advertising claims are false." *Id.* at *15.

For these reasons, Plaintiff alone bears the burden of proving that the advertised health benefits of Defendants' Product are actually false. Defendants

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[3] Even if this Court were to reject the "all scientists agree" standard from *In re GNC* and adopt the *Mullins v. Premier Nutrition Corp.*, 178 F. Supp. 3d 867, 894-95 (N.D. Cal. Apr. 15, 2016) standard that plaintiff must show "all scientists agree" to prove literal falsity or, alternatively, that the "vast majority of scientists agree" to prove something is literally true but nevertheless misleading—a case this Court should not follow because it represents a departure from established case law—the opinions of Defendants' experts and the studies they cite would still be admissible to show that Plaintiff cannot meet that standard either.

have no burden to prove anything, much less to scientifically substantiate their claims.[4]

2. *Dr. Mitmesser did not have to conduct a "totality of the evidence" analysis; she merely had to show there are studies in favor of ginkgo's efficacy.*

Plaintiff's primary rationale for excluding Dr. Mitmesser's opinions is that they purportedly do not adequately substantiate Defendants' claims. Specifically, Plaintiff complains Dr. Mitmesser selectively cites only studies which provide "proof" of the Products' claims, rather than considering the "totality of evidence" – referring specifically to the studies identified by Plaintiff's experts which suggest that the Product is ineffective. Mot. at 5. As a result of this deficiency, Plaintiff contends, Dr. Mitmesser's opinions cannot reliably answer the question of "whether Defendants' claims about [the Product] were proven and thus truthful." *Id*. at 6.

This argument in favor of exclusion fails because, quite simply, Dr. Mitmesser did not have to conduct a "totality of the evidence" analysis *for this case*. The "totality of the evidence" analysis is relevant to a *substantiation* claim, not a falsity claim. For example, the FDA Guidance, which references the "totality of the evidence" standard, states that it is "intended to describe the amount, type, and quality of evidence FDA recommends a manufacturer have to *substantiate* a claim." FDA Guidance, I.A. (emphasis added). It is thus evident that the FDA Guidance applies to lack of substantiation claims only, not falsity claims.

In this case, as noted above, Plaintiff has the burden to show that "all reasonable scientists" agree that ginkgo does not work. On the other hand, for

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[4] Nothing herein should be construed as an admission by Defendants that their claims are *not* substantiated. Defendants are merely noting that they need not prove as much in this case.

Defendants to prevail, they need only show that is **not** the case (i.e., that such universal agreement does not exist). Indeed, it is well-established that "[w]here there are studies demonstrating both the effectiveness and ineffectiveness of the Products," then, as a matter of law, "a reasonable jury could not find that the advertising claims are false. *Reed*, 2014 WL 12284044, at *15.

Ultimately, then, Dr. Mitmesser's opinions may not be excluded for purportedly failing to conduct a "totality of the evidence" test that is not required. Rather, as a matter of law, Dr. Mitmesser is permitted to opine that there are studies showing that gingko is efficacious, because such testimony is relevant to establishing that there are studies demonstrating the effectiveness of ginkgo so that a "reasonable jury could not find the advertising claims are false." *Reed*, 2014 WL 12284044, at *15. *See also Primiano v. Cook*, 598 F.3d 558, 567 (9th Cir. 2010), *as amended* (Apr. 27, 2010) ("The 'will assist' requirement, under *Daubert,* 'goes primarily to relevance.' What is relevant depends on what must be proved . . . .").[5]

B. The Studies Conducted on Diseased Subjects Upon Which Dr. Mitmesser Relies Are Relevant.

Plaintiff asserts that Dr. Mitmesser improperly relies on studies conducted upon diseased subjects, because their results are not relevant and cannot be reliably extrapolated to healthy individuals. Mot. at 6, 12-13. However, regardless of whether the results can be extrapolated,[6] the Product's demonstrated efficacy amongst the diseased population nevertheless addresses an entirely relevant – if not

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[5] Ironically, Plaintiff's concession in her motion that Dr. Mitmesser relies on studies showing that ginkgo works, Mot. at 2: is, in itself, a basis to grant Defendants' Motion for Summary Judgment. Having explicitly conceded there are studies in favor of ginkgo's efficacy, Plaintiff has effectively conceded they cannot establish falsity.

[6] This issue is discussed below at section II.D.3, *infra*.

dispositive – issue in this case.

Plaintiff chose to seek certification of a class comprised of "all consumers" – inclusive of both the healthy and cognitively impaired. Accordingly, as the Court observed, "Plaintiff's entire lawsuit rides on her claim that TruNature Gingko provides ***no*** benefits and that the statements on the product labels are false. ***The answer to these questions will be the same for the entire class.***" Order at 10 (emphasis added).

Therefore, if Plaintiff cannot overcome the positive findings in the diseased subject studies and affirmatively prove that the Product is, in fact, ineffective for that population, then Plaintiff's entire case is doomed. *Rikos v. Procter & Gamble Co.*, 799 F.3d 497, 520 (6th Cir. 2015), *cert. denied*, 136 S. Ct. 1493, 194 L. Ed. 2d 597 (2016) ("In other words, assessing this evidence will generate a common answer for the class based on Plaintiffs' theory of liability—whether Align in fact has been proven scientifically to provide digestive health benefits for anyone. **That common answer, of course, may be that Align does work for some subsets of the class**. That does not transform this classwide evidence into individualized evidence that precludes class certification, however . . . . Rather, the **more straightforward impact of this evidence is simply that it may prevent Plaintiffs from succeeding on the merits**.") (emphasis added). Dr. Mitmesser's references to the tests conducted upon the diseased subjects are thus indisputably material to this case.[7]

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[7] Plaintiff tries to avoid this conclusion by claiming Dr. Mitmesser "admitted" at deposition that "Defendant's [product] is not marketed to treat Alzheimer's or dementia and is intended for persons with healthy cognitive function or mild memory problems due to aging." Mot. at 6-7. This mischaracterizes her testimony. Read in context, her statement merely confirms the fact that the Product label does not target *any* specific population to the exclusion of another. *See* Delgado Decl. Ex. 1, Mitmesser 3/28/17 Deposition Transcript ("Mitmesser Depo. II") at 8:17-9:8 (when asked whether the label indicates that

C. Dr. Mitmesser is Well-Qualified to Opine on the Cognitivie Benefits of the Product, and Challenges to Her Qualifications and Credibility Go to the Weight, not Admissibility, of Her Opinions.

1. *Dr. Mitmesser's qualifications are more than sufficient for this case.*

It is axiomatic that "[t]he qualifications for expert witnesses under Rule 702 should be construed broadly." *Obesity Research Inst., LLC v. Fiber Research Int'l, LLC*, 2017 WL 1166307, at *2 (S.D. Cal. Mar. 29, 2017); *see also People v. Kinder Morgan Energy Partners, L.P.*, 159 F. Supp. 3d 1182, 1190 (S.D. Cal. 2016) (Rule 702 "contemplates a broad conception of expert qualifications"). As such, "arguments regarding expert's qualifications go more towards weight than admissibility because jurors can determine who is 'best' qualified." *In re Silicone Gel Breasts Implants Prods. Liab. Litig.*, 318 F. Supp. 2d 879, 889 (C.D. Cal. 2004).

Consistent with this principle, an expert who is qualified in the field generally is permitted to testify on a specific subject within that field, even if she lacks specialized training or experience in that particular topic. *See Obesity Research*, 2017 WL 1166307 at *2 ("It is an abuse of discretion for a court to disqualify an expert witness that is generally qualified" and what "Dr. Lerner lacks [in] the specialization of working with human subjects . . . would affect the weight of testimony rather than the admissibility"); *Lucido v. Nestle Purina Petcare Co.*,

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the Product is intended for a particular population – i.e., healthy persons, sick persons, or persons with Alzheimer's – Dr. Mitmesser answered accurately, "That's not indicated"). And it certainly does not establish that diseased or otherwise impaired individuals did not or could not purchase the Product. Moreover, at no time during the briefings on class certification did Plaintiff maintain – nor could she maintain – that her now-certified "all consumers" class is comprised exclusively of healthy persons.

-- F. Supp. 3d --, 2016 WL 6804576, at *8 (N.D. Cal. November 17, 2016) (citing 4–702 Weinstein's Fed. Evid. § 702.04[1][a] (stating that "it is an abuse of discretion for a trial court to exclude expert testimony solely on the ground that the witness is not qualified to render an opinion because the witness lacks expertise in specialized areas that are directly pertinent to the issues in question, if the witness has educational and experiential qualifications in a general field related to the subject matter of the issue in question")); *United States v. Boyajian*, 2013 WL 4189649, at *13 (C.D. Cal. Aug. 14, 2013) (lack of specialization "affects the weight of the expert's testimony, not its admissibility").

In this case, Dr. Mitmisser holds a Ph.D. in human nutrition. Since 2012, she has served as Director, Nutrition Research, and as Senior Director, Nutrition & Scientific Affairs, for Defendant NBTY, Inc. Prior to that, she was employed for seven years by Mead Johnson Nutrition as both Manager, Medical Communications and Manager, Global Medical Communications. In her corporate positions, Dr. Mitmesser's duties included management of nutrition research activities, as well as oversight of protocol and clinical study report development. She has authored or co-authored 19 peer-reviewed scientific articles in her field. She is also currently an Adjunct Professor at the Gerald J. and Dorothy R. Friedman School of Nutrition Science and Policy at Tufts University. Mitmesser Expert Report at Sec. I. & Ex. A thereto (Dkt. No. 185-2).

Further, Dr. Mitmesser has testified in four court cases other than the instant one. *Id*. at Sec. IV. In one recent matter, *Reed v. NBTY, Inc.*, 2014 WL 12284044, in the Central District of California, her expert opinion on behalf of NBTY, Inc. was accepted and considered by the Court in connection with its grant of summary judgment in defendant NBTY's favor. There, the plaintiff challenged the physiological health effect claims of a nutritional supplement; one of the claims at

issue was the increase in vasodilation and blood flow. *Reed*, 2014 WL 12284044, at *1.

Plaintiff challenges Dr. Mitmesser's qualifications on the grounds that she has no "experience, training or education concerning the science related to brain function." Motion at 1. Putting aside for the moment that such specialized experience would not be required, this argument is simply inaccurate. At her deposition, Dr. Mitmesser stated that, "[t]hroughout my professional career . . . I've been involved in looking at . . . the brain [and] memory . . . and how we clinically can measure, things of that nature." Delgado Decl. Ex. 1, Mitmesser Depo. II Tr. 16:24-17:17. She then described the following representative training and experience in brain function and brain function analysis that she has had:

- Took post-graduate coursework regarding the treatment of Alzheimer's disease and dementia. *Id.*, 15:5-16:15.
- Researched, wrote and interpreted clinical trials regarding the effects of cigarettes on memory and cognition function. *Id.*, 19:15-20:19.
- At Mead Johnson, involved in research on the effect of formulas and pre-natal nutrients on cognitive brain development, brain maturation, and visual acuity in fetuses, infants, and young children. *Id.*, 20:20-22:24.
- Prior to this litigation, involved in studies on behalf of NBTY about blood flow to the brain, and the effects of different ingredients and nutrients on brain function. *Id.*, 23:9-15.

2. *Dr. Mitmesser's experience and training relating to gingko prior to this litigation*

In an attempt to discredit her, Plaintiff claims that Dr. Mitmesser's "opinions concerning ginkgo were developed solely for this litigation," and that "[t]he first time" she read a study on ginkgo was at the end of 2015, a year after the instant lawsuit was filed. Motion at 1, 17. This accusation is both unavailing and false.

First, Dr. Mitmesser's supposed lack of experience or training with regard to

ginkgo specifically goes to the weight and not the admissibility of her opinions. As demonstrated above, she has sufficient training and experience on the study of brain functions and how they are impacted by nutrients and ingredients generally. Case law makes clear that an expert with general qualifications in the field is sufficiently qualified to testify about a specific subject therein, even without specialized training on that particular matter. *See Boyajian*, 2013 WL 4189649, at *13 (lack of specialization "affects the weight of the expert's testimony, not its admissibility"); *United States v. Bilson*, 648 F.2d 1238, 1239 (9th Cir. 1981) ("The absence of a specialty degree in psychology did not disqualify the psychiatrist from expressing an opinion").

Second, Plaintiff is espousing fake facts. While Dr. Mitmesser did state during her deposition that she had looked at the ginkgo studies cited in her report in late 2015 (after the lawsuit was filed), the entirety of her testimony makes clear that was **not** the first time she looked at them, as Plaintiff's contends. Rather, Dr. Mitmesser stated she reviews studies periodically in her role as Senior Director of Nutrition and Scientific Affairs. Delgado Decl. Ex. 2, Mitmesser 10/19/16 Deposition Transcript ("Mitmesser Depo. I") Tr. at 20:3-17. She also testified later, when asked if she had ever assessed the ginkgo claims **prior** to the lawsuit, that yes, she had done so at the time an NTP report challenged the safety of ginkgo. *See id.* at 191:23-194:14. As evidenced by an internal e-mail from that time period, that NTP report came out in **2013**, before this lawsuit was filed. Delgado Decl. Ex. 3.

Moreover, irrespective of whether Dr. Mitmesser began forming opinions about the cognitive benefits of ginkgo only after this litigation commenced, or specifically for this litigation, it is undisputed that all of the ginkgo studies upon which she relies were "conducted independent of the litigation." *Daubert v. Merrell Dow Pharm., Inc. ("Daubert II")*, 43 F.3d 1311, 1317 (9th Cir. 1995).

Accordingly, Dr. Mitmesser is qualified to give her expert opinions on the

cognitive benefits of the Product, and challenges regarding her subject matter-specific qualifications or credibility merely go to the weight of her opinions.

D. Challenges to Dr. Mitmesser's Methodologies and Conclusions and the Studies Upon Which She Relies Go to the Weight of Her Opinions, Not Their Admissibility.

The balance of Plaintiff's Motion contains a litany of attacks against Dr. Mitmesser's methodology and conclusions, as well as the studies upon which she relies. In virtually all instances, Plaintiff bases her attacks exclusively upon the opinions of her retained experts. Each of these attacks is addressed in turn below. Some of them are utterly baseless, because they rely on mischaracterizations and misstatements of Dr. Mitmesser's testimony or the studies she cites.

However, before delving into the specifics of each of these objections, it is important to note that Plaintiff's arguments largely implicate the weight, not admissibility, of Dr. Mitmesser's opinions. It is well-established that "[d]isputes as to the strength of [an expert's] credentials, faults in his use of [a particular] methodology, or lack of textual authority for his opinion, go to the weight, not the admissibility, of his testimony." *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1231 (9th Cir. 1998); *see also Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1143 n.8 (9th Cir. 1997) ("a jury should be able to determine whether asserted technical deficiencies undermine a survey's probative value"); *Primrose Operating Co. v. National American Ins. Co.*, 382 F.3d 546, 562 (5th Cir. 2004) (questions relating to bases and sources of expert's opinion affect weight to be assigned opinion, not its admissibility). In addition, "whether an expert's conclusions or factual assumptions should be accepted are issues that bear on the weight of the testimony, rather than on its admissibility, and may be attacked by cross examination and contrary evidence." *Copelan v. Techtronics Indus.*, 2015 WL 1886510, at *5 (S.D. Cal. Apr. 24, 2015) (*citing, inter alia*, *Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010)).

Indeed, even in cases where it would be appropriate to proceed with a "battle of the experts" amongst the parties, the court does not simply exclude one versus another – or accept the *ipse dixit* opinion of a particular expert; the preferred course is to permit the jury to resolve the conflict.[8] As the Ninth Circuit has explained, the power "to determine the victor in . . . a battle of expert witnesses is properly reposed in the jury." *Dorn v. Burlington No. Santa Fe R.R. Co.*, 397 F.3d 1183, 1195-1197 (9th Cir. 2005); *see also McClure Enterprises, Inc. v. Gen. Ins. Co. of Am.*, 2008 WL 2329190, at *3 (D. Ariz. June 4, 2008) ("disagreement between experts . . . goes to weight, not admissibility. It is left to the parties to convince the trier of fact that their expert and his methodology are more appropriate to gauge the loss in this case"). Accordingly, the mere fact that Plaintiff's experts disagree with or reject Dr. Mitmesser's opinion is not a valid basis for excluding Dr. Mitmesser.

1. *The Snitz and Dekoksy studies cited by Plaintiff are properly distinguishable.*

Plaintiff decries the fact that Dr. Mitmesser's expert report does not discuss two of Plaintiff's central studies – Snitz and Dekoksy. These two studies purportedly suggest that the Product is not effective as advertised. Mot. at 18.

However, this objection misses the mark. As discussed above, in a falsity case such as this one, it is entirely Plaintiff's burden to prove that the Product's claims are actually false; Defendants have no burden to prove anything or to substantiate their claims. Moreover, Plaintiff may not be able to carry her burden if there exists opposing scientific evidence regarding the Product's efficacy. *See*

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[8] Of course, Defendants cannot emphasize enough that this is **not** the type of case where the Court should proceed with jury trial focusing on a "battle of the experts." As Defendants explained in their Motion for Summary Judgment, where "battle of the experts" exists in a falsity case, Plaintiff loses on summary judgment.

Sec. II. A.1, *supra*. Accordingly, Defendants have no obligation to include any of the studies which support Plaintiff's contentions. Rather, it is entirely appropriate for Dr. Mitmesser to refer exclusively to studies supportive of the Product's claims as a counter-point to Plaintiff's proffered scientific evidence.

In addition, as a matter of law, experts are entitled to omit or reject opposing scientific evidence on principled grounds. *See, e.g., Barber v. United Airlines, Inc.*, 2001 WL 950885, at *2 (7th Cir. Aug. 16, 2001) (omission of contrary data requires adequate explanation). Here, the governing legal standard justifies Dr. Mitmesser's omission of the Snitz and Dekoksy studies: it is Plaintiff's burden to show falsity (i.e., that there is no disagreement among scientists), and Dr. Mitmesser is submitting opposing evidence for the trier of fact to decide if Plaintiff has met her burden of proof. *See* Delgado Decl. Ex. 1, Mitmesser Depo. II Tr. 60:11-12 ("the report was written to support the claims on our labels").

There are also principled scientific justifications for Dr. Mitmesser's omission of the Snitz and Dekoksy studies. Specifically as to the Snitz study, Dr. Mitmisser has explained that it "had significant missing data points." *Id*., Mitmesser Depo. II Tr. 66:2-19. As to both the Snitz and Kekoksy studies, she was troubled that they utilized an "intent-to-treat [ITT] population," which is susceptible to yielding unreliable false negatives because many of the subjects failed to actually take the assigned dosage of ginkgo for the duration of the test. *Id*. Indeed, even Plaintiff's biostatistician has conceded that ITT studies are "conservative" insofar as they show greater susceptibility to Type II errors (*i.e.*, a false negative where the researcher fails to find a treatment effective even though it is). Deposition Transcript of Martin Lee at 70:7-13; 82:11-18; 83:25-84:15 (Dkt. No. 172-52).

While Plaintiff is free to dispute Dr. Mitmesser's methodological critiques, these disputes ultimately go to the weight and not the admissibility of her opinions. *See, e.g., Kennedy*, 161 F.3d at 1231 ("[d]isputes as to the strength of [an expert's]

credentials, faults in his use of [a particular] methodology, or lack of textual authority for his opinion, go to the weight, not the admissibility, of his testimony"). Accordingly, Dr. Mitmesser's opinions should not be excluded.[9]

2. *Dr. Mitmesser's conclusions are consistent with the studies' findings and their authors' objectives.*

Plaintiff accuses Dr. Mitmesser of misstating the conclusions of five of the studies she relies upon – the studies conducted by Gebner, Rai, Wesnes,[10] Vorberg and Fies. Mot. at 7-9. However, upon a closer – and honest – inspection of these studies and Dr. Mitmesser's statements, it is evident that her conclusions are consistent with their authors' findings and objectives.

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[9] Plaintiff also criticizes Dr. Mitmesser for not including a "meta-analysis" study conducted by Laws, which Plaintiff claims shows that the Product is not effective. Mot. at 9. A meta-analysis is generally a review or compilation of a body of multiple studies on a subject matter. Plaintiff tries to discredit Dr. Mitmesser for allegedly testifying at deposition that meta-analyses are a "misuse" of scientific evidence. *Id*. However, this testimony is taken out of context and incomplete. What Dr. Mitmesser actually stated was that she would not rely "solely" on a meta-analysis. Delgado Decl. Ex. 2, Mitmesser Depo. I Tr. at 235:20-23. Further, as to the Laws meta-analysis that Plaintiff proffered, Dr. Mitmesser explained she would not rely on it because it evaluated ginkgo as "an *enhancer* of cognitive function," which is not marketed on the Product's label and is therefore not a relevant testing objective. *Id*., 235:4-19 ("so that's not necessarily something that we're going after, is to enhance") (emphasis added).

[10] With respect to the Gebner, Rai and Wesnes studies, Plaintiff insinuates that they are somehow less reliable than opposing studies cited by Plaintiff's experts because the latter are "more recent" in vintage. Mot. at 9. However, the law is clear there is no principled reason to discredit, much less reject, an older study in favor of a more recent one simply because of their age difference. *See, e.g., Sonner v. Schwabe N. Am., Inc.*, 2017 WL 474106, at *6 (C.D. Cal. Feb. 2, 2017) ("no support for the assertion that experts must always rely upon the most recent studies to reach a conclusion").

Gebner Study: Dr. Mitmesser's report describes this study as follows: "This study provides evidence for the fact that Gingko can help support healthy brain function." Mitmesser Expert Report, at Sec. III.B.1.e. (Dkt. No. 185-2). This description ***tracks the conclusion*** written by the study's authors, which states, in part: "The results show that chronic G.B.E. medication has a positive effect in geriatric subjects with deterioration of mental performance and vigilance . . ." Gebner Study at 1460 (Dkt. No. 181-2). Plaintiff takes issue with the fact that these results are the secondary findings of the study. Mot. at 7-8. That is a distinction without a difference. Moreover, even if Plaintiff's argument is credited, the question of whether Dr. Mitmesser's conclusion is properly supported by Gebner's study goes to the weight, and not the admissibility, of Dr. Mitmesser's opinion. *See, e.g., Hartley v. Dillard's, Inc.,* 310 F.3d 1054, 1061 (8th Cir. 2002) ("the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination").

Rai Study: Dr. Mitmesser's report describes this study as follows: "This study provides evidence for the fact that Gingko can help support memory." Mitmesser Expert Report, at Sec. III.B.1.j (Dkt. No. 185-2). Plaintiff objects to this description because the Rai study in fact yielded "contrasting results regarding the efficacy of GB" – i.e., some results supported the Product's claims while others did not – but Dr. Mitmesser did not mention the negative results in her report. Mot. at 8. However, as discussed earlier, given that the governing legal standard imposes the burden of proof entirely upon Plaintiff to establish falsity, Dr. Mitmesser is under no obligation to proffer negative findings, and she may appropriately highlight counter-evidence which support the Product's claims. In any event, this issue ultimately goes to the weight of Dr. Mitmesser's opinions, and Plaintiff is free to test her credibility on cross-examination. *See, e.g., Hartley.,* 310 F.3d at 1061 ("the factual basis of an expert opinion goes to the credibility of the

testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination").

Wesnes Study: Plaintiff challenges Dr. Mitmesser's reliance on this study because it utilizes a certain statistical technique called the "one-tailed t-test." Plaintiff's experts apparently believe that this technique is unreliable. Mot. at 8-9. However, regardless of the merits of this dispute, it is a methodological dispute, which ultimately goes to the weight but not admissibility of Dr. Mitmesser's opinion. *See Kennedy*, 161 F.3d at 1231 (methodology questions go to weight, not admissibility).

Vorberg Study: Dr. Mitmesser's report describes this study as follows: "This study provides evidence of increased blood flow to the brain which helped ameliorate the various symptoms that had resulted from insufficient blood flow to the brain." Mitmesser Expert Report, at Sec. III.B.1.a. (Dkt. No. 185-2). Plaintiff alleges that this is an inaccurate conclusion because Vorberg's findings supposedly never mention blood flow to the brain. Mot. at 10. Plaintiff is wrong. Vorberg's study notes that the "objective of the study was to test the effects of GBE therapy on symptoms of cerebal insufficiency."[11] Vorberg Study at 149 (Dkt. No. 172-4). With respect to its findings, the study states that the "good therapeutic results" observed in testing "may possibly be explained by an improvement in global and regional ***blood-flow in the brain***…." *Id*. at 156 (emphasis supplied). Vorberg provides no other explanation as to what could be responsible for the positive results found. *Id*. Accordingly, Dr. Mitmesser's conclusion is consistent with the authors' analysis. In any event, Plaintiff's objection to Dr. Mitmesser's

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[11] Cerebral insufficiency or cerebrovascular insufficiency "refers to a number of rare conditions that result in obstruction of one or more of the arteries that supply blood to the brain." http://www.hopkinsmedicine.org/neurology_neurosurgery/centers_clinics/cerebrovascular/conditions/cerebrovascular_insufficiency.html.

conclusions about the Vorberg study ultimately goes to weight, not admissibility. *See Copelan v. Techtronics Indus.*, 2015 WL 1886510, at *5 ("whether an expert's conclusions or factual assumptions should be accepted are issues that bear on the weight of the testimony, rather than on its admissibility, and may be attacked by cross examination and contrary evidence").

Fies Study: Dr. Mitmesser's report describes this study as follows: "This study provides evidence for increased blood flow to the eyes which would also be indicative of increased blood flow to the brain." Mitmesser Expert Report, at Sec. III.B.1.c. (Dkt. No. 185-2). Plaintiff alleges that Dr. Mitmesser misstates Fies' findings because the study supposedly never mentions blood flow to the eyes. Mot. at 10. Plaintiff is mistaken. The study found there was meaningful improvement in the vision of the subjects to whom ginkgo was administered. In explaining this result, the authors of the study referenced the "proven therapeutic effects" of ginkgo in patients who have poor blood circulation to the brain, as well as pharmacological studies which show that ginkgo influences the "circulation capacity of blood." Fies Study at 7 (Dkt. No. 172-6). Accordingly, there is an existent "supposition" that ginkgo is "expected to have" beneficial effects on disorders of the retina, given the "close histopathological correlation between cerebral and retinal vascular supply" – a supposition that has been "repeatedly substantiated" by previous studies conducted on subjects with various retinal disorders. *Id*. The authors went on to conclude that the results of their study – i.e., improved vision exhibited by those administered various dosages of ginkgo – "confirms previous clinical empirical results." *Id*. at 8. In any event, Plaintiff's objection to Dr. Mitmesser's conclusions about the Fies study ultimately goes to weight, not admissibility. *See Copelan,* 2015 WL 1886510, at *5 ("whether an expert's conclusions or factual assumptions should be accepted are issues that bear on the weight of the testimony, rather than on its admissibility, and may be attacked by cross examination and contrary evidence").

3. *Plaintiff mischaracterizes Dr. Mitmesser's opinion regarding studies conducted upon diseased subjects.*

Dr. Mitmesser relies upon multiple studies conducted upon diseased subjects (e.g., individuals suffering from Alzheimer's or dementia) which support the Product's claims regarding cognitive benefits. Plaintiff attacks these studies on the grounds that their results cannot be extrapolated to the healthy population. However, as discussed earlier, this objection is unavailing because Plaintiff has the burden of proving that the Product's claims are false as to "all consumers" – both the healthy and the sick. Therefore, if Plaintiff is unable to establish falsity even just as to the diseased population, her entire lawsuit fails.

But beyond that, Plaintiff's critique is also disingenuous. She claims Dr. Mitmesser has admitted that the results of studies conducted upon diseased subjects have no bearing on the healthy population. She cites as proof a passage in Dr. Mitmesser's deposition in which she responded to a hypothetical question and agreed that studies purporting to show ginkgo's efficacy "*in the treatment of*" Alzheimer's or dementia cannot be relied upon to reach conclusions about its effects on the healthy population. Mot. at 12, *citing* Mitmesser Depo. II Tr. at 102:10-21 (emphasis supplied). However, Plaintiff is using this quote out of context to give a misleading impression. Prior to that passage in her deposition, Dr. Mitmesser made clear that the Product was never intended or marketed to "*treat*" any disease, including Alzheimer's and dementia. Delgado Decl. Ex. 1, Mitmesser Depo. II Tr. at 48:17-23 (emphasis added). As such, it is unsurprising that Dr. Mitmesser would decline to rely on any study that purports to support the use of the Product as a "treatment" for disease.

What Dr. Mitmesser also said is that, as distinguished from the treatment of disease, there is reliable evidence of ginkgo's ability to "support the improvement of the *symptoms*" of diseases such as dementia or Alzheimer's, which have symptoms that include diminished memory, recognition, and recall. *Id*. at 42:18-

22 (emphasis added). And, she further explained, ginkgo's demonstrated capacity to help ameliorate the cognitive symptoms of those with a "stressed system" – i.e., suffering from diseases like Alzheimer's or dementia – can assist in our understanding of how the substance may react in, and provided benefits to, a healthy person. *Id*. at 49:5-50:3.[12] Accordingly, Dr. Mitmesser has not contradicted herself in regards to the relevance of the studies conducted upon the diseased population.

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[12] Plaintiff also levels the accusation that Dr. Mitmesser disagrees with certain recommendations of the Alzheimer's Association ("AA") regarding ginkgo. Motion at 12-13. This is misleading. At her deposition, Plaintiff's counsel asked her a vague question about whether she would agree with the AA's purported recommendation that ginkgo should not be taken "for Alzheimer's," to which Dr. Mitmesser replied that she would disagree. Delgado Decl. Ex. 1, Mitmesser Depo. II Tr. at 107:21-25. Within the context of the questioning, Dr. Mitmesser understood the phrase "for Alzheimer's" to mean using ginkgo "in the treatment of some *symptoms* of Alzheimer's," and as such, her response is consistent with the scientific data she has reviewed. *Id*. at 107:7-20 (emphasis supplied). Moreover, there is no real disagreement between her and the AA. The text of AA's actual policy statement on this issue – a copy of which counsel refused to show Dr. Mitmesser at her deposition, even though she indicated she was not familiar with it – reveals Plaintiff's counsel misrepresented its contents.

Specifically, the AA's statement recommends against the use of ginkgo as an alternate "treatment[]" for Alzheimer's, but it recognizes that it "may have positive effects on cells within the brain and body," and it further acknowledges that ginkgo is "being used in Europe to alleviate cognitive symptoms associated with a number of neurological conditions." Alzheimer's Association, *Alternative Treatments*, http://www.alz.org/alzheimers_disease_alternative_treatments.asp (Dkt. No. 179-15).

Had Plaintiff's counsel shown Dr. Mitmesser a copy of the AA's actual recommendation at her deposition, she would have assuredly agreed with it.

III. CONCLUSION

For all of the foregoing reasons, Plaintiff's Motion should be denied in its entirety.

Dated: May 23, 2017

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